Ramon Rossi Lopez – rlopez@lopezmchugh.com
(California Bar Number 86361; admitted *pro hac vice*)
Lopez McHugh LLP
100 Bayview Circle, Suite 5600
Newport Beach, California 92660
949-812-5771

Mark Stephen O'Connor (011029) – mark.oconnor@gknet.com
Gallagher & Kennedy, P.A.
2575 East Camelback Road
Phoenix, Arizona 85016-9225
602-530-8000

Julia Reed Zaic, Esq. – julia@hrzlaw.com
(California Bar Number 224671; admitted *pro hac vice*)
Laura Smith, Esq.
(California Bar Number 313879; admitted *pro hac vice*)
Heaviside Reed Zaic
312 Broadway, Suite 203
Laguna Beach, California 92660
949-715-5120

Counsel for Plaintiffs

UNITED STATES DISTRICT COURT

DISTRICT OF ARIZONA

In Re Bard IVC Filters Products Liability Litigation	No. MD-15-02641-PHX-DGC **PLAINTIFFS' RESPONSE IN OPPOSITION TO DEFENDANTS' MOTION FOR SUMMARY JUDGMENT REGARDING PREEMPTION** (Assigned to the Honorable David G. Campbell) **(Oral Argument Requested)**

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Pursuant to Rule 56(c), Federal Rules of Civil Procedure; Local Rule 56.1; and Case Management Order No. 26 (Doc. 6799), Plaintiffs oppose Defendants' Motion for Summary Judgment Regarding Preemption ("Motion"). Despite the sheer volume of paper Bard submitted in support of its Motion, the fact remains that none of the state court causes of action in this case are preempted, and well-reasoned precedent requires this Court to deny Bard's motion.

This response is supported by the following Memorandum of Points and Authorities, Plaintiffs' Separate Statement of Facts ("SSOF") and the exhibits thereto, and Plaintiffs' Controverting Statement of Facts ("CSOF") and the exhibits thereto.

MEMORANDUM OF POINTS AND AUTHORITIES

I. INTRODUCTION AND SUMMARY OF ARGUMENT

Bard's Motion fails because the 510(k) FDA review process for its IVC filters neither created device-specific federal requirements nor came close to the rigorous pre-market safety and efficacy approval process for which express preemption may apply. There is nothing novel about this medical device litigation or the 510(k) "substantial equivalence" FDA review that cleared Bard's IVC filters for sale that distinguishes this case from the many others in which preemption challenges related to 510(k)-cleared devices have been nearly universally denied under longstanding Supreme Court precedent.

Bard must carry the burden of proof to establish preemption. State law tort claims involving 510(k)-cleared medical devices are not preempted under the express preemption clause[1] of the Medical Device Amendments 1976 ("MDA") to the Federal Food Drug and Cosmetic Act ("FDCA") unless: (1) the federal government promulgates a specific counterpart regulation or requirement applicable to a particular device; *and* (2) state law is different from, or in addition to, those promulgated requirements. 21 C.F.R. § 808.1(d);[2] *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 321-322 (2008). Bard's IVC filters do not meet this

[1] 21 U.S.C. § 360k(a).

[2] Bard fails to cite this federal regulation which the Supreme Court has consistently recognized as informing the express preemption clause when addressing preemption challenges related to medical devices. *Riegel*, 552 U.S. at 322; *Medtronic Inc. v. Lohr*, 518 U.S. 470, 498 n. 18 (1996).

standard. The federal government has not promulgated any device-specific requirements for retrievable IVC filters so there can be no careful comparison between the allegedly preempting federal requirement and the allegedly preempted state law to determine whether the state law claims fall within the scope of the MDA's express preemption clause, 21 U.S.C. § 360k(a).

Nonetheless, Bard seeks complete express preemption of all state law tort liability claims[3] under a self-created standard cobbled together from a lengthy (and conspicuously over-stated) recitation of mostly administrative, logistical, and ordinary interactions with the FDA typical of a 510(k) review. Bard attempts to demonstrate that the ordinary 510(k) review processes that its IVC filters underwent were so exceptional that they somehow created device-specific requirements on par with those described in 21 C.F.R. § 808.1(d). Yet even if Bard could establish that the 510(k) review of its filters was abnormally rigorous or otherwise unusual (which is not the case), its flawed premise has already been rejected by the Supreme Court. The Court has stated unequivocally that federal requirements are neither imposed nor created during the FDA's 510(k) pre-market notification review process, as opposed to the review FDA undertakes when examining a pre-market approval (PMA) submission for which preemption has been found by some courts to apply.

Bard's motion also fails because it offers no evidence establishing that the 510(k) review processes for Bard's IVC filters—even with special controls—were equivalent to the rigorous PMA review process such that express preemption applies. *See Riegel*, 552 U.S. 322-23 (distinguishing between PMA and 510(k) review). Moreover, even if there were such evidence before the Court, Bard has not explained how any allegedly preempted state laws are different from, or in addition to, any allegedly existing federal requirements.

Finally, numerous courts have rejected the exact implied preemption argument that Bard now makes. For these reasons, and as discussed more fully below, Bard's motion for summary judgment based on federal preemption should be denied.

[3] A complete list of Plaintiffs' causes of action can be found in the Master Complaint (Doc. 303-1).

II. PLAINTIFFS' SEPARATE STATEMENT OF UNDISPUTED FACTS

Under the MDA, devices that undergo PMA review are deemed "approved" by the FDA, and those that undergo 510(k) review are not approved but rather "cleared" by the FDA because they are substantially equivalent to a predicate device already on the market. *See* SSOF 1-5. All of Bard's IVC filters at issue were cleared via 510(k) review between Nov. 27, 2002,[4] and May 15, 2013. SSOF 6-7. None were approved by the FDA via PMA review. SSOF 4, 42. Bard's former Vice President of Regulatory Sciences (2003-2007) acknowledges that when a device is cleared through the 510(k) process it is not a determination that the FDA deems the device to be safe and effective. SSOF 11. Rather, the purpose of 510(k) clearance review is solely to determine if a device is substantially equivalent to a predicate medical device already on the market. SSOF 11, 15. Thus, the FDA has *never* found, held, or determined that the IVC filters at issue in this litigation were safe and effective. In fact, none of the predicate devices for any of Bard's IVC filters, or the predicates for those predicates, was ever independently approved by the FDA as safe and effective; they were compared and deemed substantially equivalent to a predicate device. SSOF 72.

Bard maintained control over its 510(k) submissions and could withdraw its submissions at any time, as it did voluntarily with 510(k) number K090392. SSOF 36. Of the fifteen 510(k) submissions Bard cites, only ten involved the filters themselves; the extraneous five were 510(k) submissions[5] related to changes in brochures or the modifications of the delivery systems which do not remain in the body. SSOF 7-8.

The FDA's clearance letters establish only that Bard's IVC filters are: (1) 510(k)-cleared; (2) found (based on Bard-provided information) to be substantially equivalent to a predicate device; (3) subject to general controls and any applicable special controls; and (4) further distinguished from PMA-approved devices. SSOF 6, 10. Language found in Bard's IFUs for its IVC filters was not mandated by Congress or the FDA, but was part of

[4] Bard's first 510(k) submission for its original retrievable filter, the Recovery, was in November 1999, but due to overwhelming deficiencies it did not receive clearance. *See* Carr Dec., Ex. 1-2.

[5] These submissions were presumably included to support Bard's "this-much-paper-must-mean-preemption" analysis.

negotiations with the FDA during the 510(k) review process, during which Bard can choose to accept or reject language proposals from the FDA. SSOF 14, 50. The FDA's guidance document for IVC filters does not contain device-specific labeling regarding the filter complications and resulting injuries suffered by Plaintiffs at issue in this litigation. SSOF 24-27; 34. This self-described "*guidance*" document is not deemed a federal requirement. SSOF 24; *see, e.g.*, *Thompson v. DePuy Orthopaedics, Inc.*, 2015 WL 7888387, at *10 (S.D. Ohio 2015). In fact none of the three documents assigned to IVC filters as special controls via 21 C.F.R. § 870.3375 contain device-specific requirements or recommendations, including as to Bard's IVC filters. SSOF 19-42.

All additional information the FDA requested of Bard during the 510(k) review process for each of its filters, including clinical data, was to support a determination of substantial equivalence to a predicate device. SSOF 12, 13, 44. There are no performance standards or design controls promulgated by Congress or FDA specific to any IVC filter, as Bard itself confirms. SSOF 47-48. And Bard's clinical experience with its retrievable filters consists of only short-term, uncontrolled clinical studies addressing only placement and retrievability. SSOF 45, 51-53. Bard also withheld key information from the FDA about the safety of its retrievable filters. SSOF 54-66, 71.

In short, Bard's filters were reviewed only under the 510(k) substantial equivalence process and were not subject to federal device-specific requirements.

III. ARGUMENT

A. The summary judgment standard.

Summary judgment is appropriate "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). The movant also "bears the initial responsibility of informing the district court of the basis for its motion, and identifying those portions of [the record] which it believes demonstrate the absence of a genuine issue of material fact." *Celotex Corp. v. Catrett*, 477 U.S. 317, 323, (1986). Disputed facts that might "affect the outcome of the suit will preclude the entry of summary judgment, and the disputed evidence must be 'such that a reasonable

jury could return a verdict for the nonmoving party.'" *Placencia v. I-Flow*, 2012 WL 5877624 (D. Ariz. 2012) (quoting *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248, (1986)).[6]

B. Overview of the MDA and preemption.

Bard's principal argument is that the well-reasoned and longstanding distinction between PMA review of medical devices (for which preemption has been found) and 510(k) clearance of medical devices (for which preemption is generally not afforded) recognized in *Lohr* and *Riegel* is no longer viable given changes to the MDA in 1990. As the following overview demonstrates, Bard is mistaken.

1. The SMDA of 1990 did not alter the express preemption clause that has remained in effect for forty years.

Congress granted the FDA authority to regulate medical devices and adopted a general prohibition on non-federal regulation by incorporating an express preemption clause into the MDA. Pub. L. No. 94-295, 90 Stat. 539 (1976). While the MDA underwent alterations with the enactment of the Safe Medical Devices Act of 1990 (SMDA), the express preemption clause did not change, and has not changed despite Congress's multiple re-reviews of the Act. *See* Chart 1, *infra*.

Chart 1 – Express Preemption Language, Section 521a, 21 U.S.C. § 360k

Food, Drug and Cosmetic Act of 1938 (FDCA)	**Medical Device Amendments of 1976** (MDA)	**Safe Medical Device Amendments of 1990** (SMDA)	**FDA Modernization Act of 1997** (FDAMA)	Medical Device User Fee and Modernization Act of 2002 (MDUFMA)	Medical Device User Fee and Stabilization Act of 2005 (MDUFSA -I)	Medical Device User Fee and Stabilization Act of 2012 (MDUFSA - II)
ENACTED	Express Preemption Language at Section 521a (21 U.S.C. 360k)	No change.	No change.	No change.	No change.	No change.

[6] Bard, in arguing against summary judgment on its government rules defense in *Austin v. Bard*, claimed that whether safety and efficacy underlie the 510(k) process creates a genuine issue of fact precluding summary judgment. SSOF 73, Ex. 2 at Ex. Z. Summary judgment should be denied as a matter of law here given the failure of Bard to establish the applicability of express or implied preemption. However, at worst, under Bard's own admission, a material issue of fact concerning the scope of 510(k) review would preclude summary judgment for Bard.

In fact, it has been over four decades since the 1976 Amendments were enacted adding this express preemption language, and two Supreme Court opinions have interpreted it in the 510(k) and PMA context. The law has not changed and, if anything, is further informed by 21 C.F.R. § 808.1(d) as to its scope. *Riegel*, 552 U.S. at 322.

Additionally, in determining that the MDA is not device-specific (i.e., it applies to all medical devices) and consists purely of "general controls," *Lohr* recognized the Congressional narrowing of the preemption clause via FDA regulations, stating "state requirements are pre-empted 'only' when the FDA has established 'specific counterpart regulations or . . . other specific requirements applicable to a particular device.'" *Medtronic, Inc. v. Lohr*, 518 U.S. at 498 (quoting 21 C.F.R. § 808.1(d) (1995)); *see also*, *Riegel*, 552 U.S. at 322. This limitation on the express preemption clause in § 360k(a) has been widely recognized pre- and post-*Riegel/Lohr*.[7] It is considered an implementing regulation. *Perez v. Nidek Co., Ltd*., 711 F.3d 1109, 1117 (9th Cir. 2013). In this sense, Congress has shortened the reach of the express preemption clause for 510(k)-cleared devices. *See James v. Diva Intern., Inc.*, 803 F. Supp. 2d 945, 950 (S.D. Ind. 2011); *see also Thompson*, 2015 WL 7888387, at *8.

2. The SMDA of 1990 downgraded regulatory controls from device-specific "performance standards" to "special controls" which (as here) do not always contain device-specific information.

Prior to the SMDA's enactment in 1990, the MDA required the FDA to promulgate performance standards specific to all Class II devices cleared through the 510(k) process. *See* Pub. L. 94-295, 90 Stat. 541 (1976); SSOF 9. Yet this proved to be an onerous process that never came to fruition. *Id.* The initial House Report on the bill explained that one purpose of the 1990 revisions was to do away with the performance standards requirement to better protect the public:

> Since the comprehensive medical device law was enacted in 1976, difficulties have persisted in the *implementation* of the law. These implementation problems appear to be the result of: (1) complexities in the law; (2) the manner in which FDA interpreted certain provisions of the 1976 law; and (3) limited resources. The

[7] *See, e.g., Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 736, 752 (S.D. W. Va. 2014); *James v. Diva Intern., Inc.*, 803 F. Supp. 2d 945, 951-52 (D. Ind. 2011); *Poole v. Hologic*, 2010 WL 3021528, at *3 (W.D. La. 2010); *Elbert v. Howmedica, Inc*., 841 F. Supp. 327, 330-32 (D. Haw. 1993); *Murray v. Medtronic, Inc*., 1993 WL 515741, at *1-2 (E.D. La. Dec. 3, 1993).

> purpose of this legislation is to modify the underlying law in ways that will result in greater protection of the public health."

H.R. Rep. No. 101-808, § 13 (1990) (emphasis added). So the SMDA of 1990 substituted "special controls" for "performance standards" for Class II devices. *See* Pub. L. 101-629, 104 Stat. 4511 (1990). These amendments created a less administratively burdensome process on the resource-limited FDA by switching from a requirement to promulgate performance standards for individual medical devices to instead assigning special controls. SSOF 9. Special controls do not necessarily contain device-specific or disease- specific information or performance standards associated with design or use of a product. *Thompson*, 2015 WL 7888387, *10 (stating that special controls in the form of guidance documents may provide recommendations for 510(k) submissions but do not necessarily mandate any particular performance standards).

The SMDA of 1990's changes to the MDA, downgrading from the FDA's promulgation of device-specific performance standards to special controls which are not necessarily device–specific or disease-specific, undermines Bard's contention that the SMDA of 1990 "thoroughly overhauled" the MDA. Motion at 11. Instead, the pre-SMDA of 1990 device-specific performance standards were *relaxed* in order to make clearance of 510(k) devices less administratively burdensome on the FDA. SSOF 9.

The Supreme Court has recognized that the SMDA of 1990 was designed to reduce the FDA's reliance on the 510(k) process, reflecting that most devices avoided PMA review by using 510(k) review. *Lohr*, 518 U.S. at 479. The Court also recognized, however, that six years after the enactment of the SMDA of 1990 the "lopsidedness has apparently not evened out." *Lohr*, 518 U.S. at 479. Eighteen years after the SMDA of 1990, the Supreme Court continued to note the imbalance between devices "cleared" via the 510(k) substantial equivalence review and "approved" via PMA.[8] The Supreme Court in *Lohr* may have been examining a record involving a pre-SMDA 1990 510(k)-cleared medical device, *e.g.*, Motion

[8] "Most new Class III devices enter the market through § 510(k). In 2005, for example, the FDA authorized the marketing of 3,148 devices under § 510(k) and granted premarket approval to just 32 devices." *Riegel*, 552 U.S., at 317 (citing P. Hutt, R. Merrill, & L. Grossman, *Food and Drug Law* 992 (3d ed. 2007)).

at 11, but it evaluated the preemption clause as it exists today unchanged since 1976, and is affected only by 21 C.F.R. § 808.1(d).

3. The Supreme Court defined the scope of express preemption in *Lohr* and *Riegel*: 510(k) review does not set a federal requirement for safety and effectiveness.

The 510(k) review process does not set federal requirements. *Riegel*, 552 U.S. at 322; *Placencia*, 2012 WL 5877624, at *5. That is because devices entering the market solely based on having met the substantial equivalence standard of 510(k) review have "never been formally reviewed under the MDA for safety or efficacy" and do not require the strict adherence to specifications in their applications that PMA-approved devices do. *Riegel*, 552 U.S. at 323 (quotation marks omitted).

In *Lohr*, the plaintiff's common law negligence and strict liability claims against the defendant were not preempted because the Court found that the 510(k) review process does not include or create federal "requirement[s]" that could conflict with state law claims. 518 U.S. at 486-87. The Court observed that the 510(k) process, unlike the PMA review process, "is focused on *equivalence*, not safety," and therefore "substantial equivalence determinations provide little protection to the public." *Id.* at 493 (emphasis in original). Moreover, "[n]either the statutory scheme nor legislative history suggests that the § 510(k) process was intended to do anything other than maintain the status quo, which included the possibility that a device's manufacturer would have to defend itself against state-law negligent design claims." *Id*. at 494. Almost ten years after its decision in *Lohr*, the Court again reiterated its view that the FDA's 510(k) review is based on "substantial equivalence" and not "safety," and therefore 510(k) review did not establish device-specific-requirements supporting preemption. *Riegel*, 552 U.S. at 317, 323. The Court found:

> Even though substantial-equivalence review under § 510(k) is device specific, *Lohr* also rejected the manufacturer's contention that § 510(k) approval imposed device-specific "requirements." We regarded the fact that products entering the market through § 510(k) may be marketed only so long as they remain substantial equivalents of the relevant pre-1976 devices as a qualification for an *exemption rather than a requirement.*

552 U.S. at 322 (emphasis added).

In fact, "FDA regulations explicitly prohibit manufacturers of devices that have reached the market through the § 510(k) process from indicating that the FDA has actually approved their device on the merits . . . ." *Riegel*, 451 F.3d 104, 112 (2d Cir. 2006), *aff'd* 552 U.S. 312 (2008). The sole purpose and effect of the FDA's 510(k) review, as opposed to PMA approval, is to establish that the new device has the same intended use as the predicate device, and has the same technological characteristics. 21 U.S.C. § 360c(i); *see also* 21 C.F.R. §807.97 (noting that FDA clearance of a 510(k) submission "does not in any way denote official approval of the device."). Therefore, it is the general rule, not the exception, that state tort claims involving 510(k)-cleared devices are not preempted.

While the goal of the MDA and its amendments is to protect public safety, it provides different levels of review which ultimately have different regulatory and legal standards. *See* 21 U.S.C. § 360c. "Thus, even though the FDA may well examine[s] § 510(k) applications . . . with a concern for the safety and effectiveness of the device," that review does not require a 510(k) device "to take any particular form for any particular reason." *Lohr*, 518 U.S. at 493.

Following *Lohr* and *Riegel*, courts have consistently confirmed that 510(k) review does not establish federal requirements to refute medical device manufacturers' arguments that the pre-1990 510(k) clearance process is outdated. *See In re: C.R. Bard, Inc. MDL No. 2187, Pelvic Repair System Products Liability Litigation (Cisson)*, 810 F.3d 913 (4th Cir 2016) [hereinafter "*Cisson*"] (clearing a product through the 510(k) process is "a qualification for an exemption rather than a requirement." (citing *Riegel*)); *Horillo v. Cook, Inc.*, 2014 WL 8186704, at *3 (S.D. Fla. 2014). This is in part because the 510(k) review "process impose[s] no requirements with respect to the design of the device." *See also Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 736, 752 (S.D. W.Va. 2014), *aff'd* 848 F.3d 151 (4th Cir. 2017) (stating that 510(k) process does not set forth "specific requirements").

The FDA itself has embraced the very distinction enunciated by *Lohr* and *Riegel*. Indeed, in every 510(k) clearance letter issued for Bard's retrievable IVC filters, the FDA admonished Bard that 21 C.F.R. § 807 must be complied with, which includes 21 C.F.R. § 807.97. *Id.* (stating that clearance of a 510(k) submission "does not in any way denote official

approval of the device. Any representation that creates an impression of official approval of a device because of complying with the premarket notification regulations is misleading and constitutes misbranding.").

Lohr and *Riegel* still control when reviewing preemption challenges involving 510(k) devices and there is no controlling authority to the contrary. Indeed, as the *Horillo* court found, Bard's arguments that the *Lohr* analysis is outdated and that the post-SMDA of 1990 process for 510(k) clearance is more akin to PMA must be rejected in the absence of controlling authority overruling *Lohr* and *Riegel*. 2014 WL 8186704 at *3 (stating that where no legal authority exists beyond a law journal article and without sufficient evidence, courts cannot contradict Supreme Court express preemption rulings as to 510(k)-cleared devices).[9]

C. Express preemption and 510(k)-cleared medical devices.

The MDA only expressly preempts certain state laws under certain circumstances:

> (a) Except as provided in subsection (b), no state or political subdivision may establish or continue in effect with respect to a device intended for human use any requirement—
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a). Thus whether a medical device is preempted under the MDA is a two-question test: (1) Has the federal government created a federal requirement specific to a particular device, and (2) does a state's law create requirements different from, or in addition to, those requirements? *Riegel*, 552 U.S. at 321-324; *Arvizu v. Medtronic, Inc*., 41 F. Supp. 3d 783, 787 (D. Ariz. 2014). The first question asks whether the federal government has established requirements applicable to the device at issue: Bard's IVC filters. *Riegel,* 552 U.S. at 321-322. Such requirements are "substantially informed" by FDA regulations, specifically 21 C.F.R. § 808.1(d). *Id.* at 322. Consequently, state-law claims are only preempted under two circumstances:

> (d) State or local requirements are preempted **only** when the FDA has established ***specific counterpart regulations*** **or** there are ***other specific requirements***

[9] The defendants in *Horillo* cited the same law journal article to which Bard cites on page 15 of its Motion.

> ***applicable to a particular device under the act***, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific Food and Drug Administration requirements.

21 C.F.R. § 808.1(d) (emphasis added). Thus, under the first inquiry, devices subject to counterpart regulations are preempted only if the promulgated counterpart regulation speaks to the requirements imposed by a state's law.[10]

As to the second circumstance under 21 C.F.R. § 808.1(d), even when there is no counterpart device-specific regulation promulgated, PMA approval imposes "requirements" under the MDA because PMA approval is not "an exemption from federal safety review" like the 510(k) review process but rather, "it *is* federal safety review." *Riegel*, 552 U.S. at 322-23 (emphasis in original). Therefore, unlike 510(k) clearance, PMA approval of a device itself creates a specific federal requirement under the second circumstance of 21 C.F.R. § 808.1(d).

Once it is determined whether a federal requirement specific to a device exists—either via a counterpart regulation or through PMA review—the second question of the preemption test requires a court to determine if the state law claims create requirements in addition to, or different from, any requirement applicable under the Act. *Id.* at 322-323.

D. Bard fails the two-part preemption test because there are no specific federal requirements for its IVC filters, and, even if there were, Bard has not done a careful comparison between alleged federal requirements and allegedly preempted state law.

As discussed, whether a medical device is preempted under the MDA is a two-question test: (1) has the federal government created a federal requirement specific to a particular device, and (2) does a state's law create requirements different from, or in addition to, those requirements? *Riegel*, 552 U.S. at 321-324. The first of these questions itself has two parts as set forth in 21 C.F.R. § 808.1(d), because that regulation allows preemption of state law claims under only two circumstances: (1) if the FDA has established specific

[10] For example, where a counterpart regulation addresses warning language that is disease-specific, failure to warn claims are subject to preemption, but where the regulation is silent as to design, design defect claims survive preemption challenges. *Papike v. Tambrands Inc.*, 107 F.3d 737, 740-41 (9th Cir. 1997) (differentiating between regulation with specific warning language as preemptive of failure to warn claims and where preemption challenge fails as to design defect claims when regulation is silent as to design); *see also Moore v. Kimberly-Clarke*, 867 F.2d 243, 246 (5th Cir. 1989).

counterpart regulations, or (2) there are "other specific requirements applicable to a particular device" under the MDA.

Bard has not shown that under 21 C.F.R. § 808.1(d) there are any counterpart federal regulations that establish any federally-required warning language, design specifications, performance or testing standards, design controls, or any other requirements pertaining to its IVC filters that would preempt Plaintiffs' state law claims. And, because the 510(k) review process does not include or create federal "requirement[s]" as defined in the express preemption clause of the MDA, *Lohr*, 518 U.S. at 486-87, Bard's preemption argument fails at the outset.

1. Bard fails the first component of 21 C.F.R. § 808.1(d) because there are no counterpart regulations associated with any IVC filter.

a. Special controls are not federal requirements.

Bard's preemption argument is predicated on its contention that special controls are akin to federal requirements from which preemption may flow. Bard is wrong.

FDA assigned three documents to serve as "special controls" for all IVC filters via 21 C.F.R. § 870.3375:

- ISO 10993 Biological Evaluation of Medical Devices Part I: Evaluation and Testing;
- FDA's 510(k) Sterility Review Guidance and Revision (Feb. 12, 1990) (K90-1);
- FDA's Guidance for Cardiovascular Intravascular Filter 510(k) Submissions (Nov. 26, 1999).

As this case illustrates, special controls are not necessarily federal "requirements" for which preemption may apply. A "requirement" is defined as "a rule of law that must be obeyed." *Bates v Dow Agrosciences, LLC*, 544 U.S. 431, 445 (2005). Regulations such as 21 C.F.R. § 870.3375 promulgated merely for the purposes of identification are not substantive federal requirements. *Anguiano v. E.I. Du Pont De Nemours & Co., Inc.*, 44 F.3d 806, 810 (9th Cir. 1995) (stating "Class II devices . . . must carry some specific regulation beyond the identification regulation for preemption to apply"); *Ginochio v. Surgikos, Inc.*, 864 F. Supp. 948, 953 (N.D. Cal. 1994); *Elbert v. Howmedica, Inc.*, 841 F. Supp. 327, 331 (D. Haw. 1993).

Therefore, although 21 C.F.R. § 870.3375 identifies special controls for all IVC filters, it is not a device-specific counterpart regulation under 21 C.F.R. § 808.1(d). *Cf. Papike*, 107 F.3d at 740-41 (citing 21 C.F.R. § 801.430 with specific substantive warning language that is device-specific and disease-specific to tampons and Toxic Shock Syndrome).

Absent device-specific counterpart regulations, federal "requirements" under 21 C.F.R. § 808.1(d) are described in *Lohr* as originating from two sources: (1) federal safety review established under the rigorous PMA approval process, and (2) requirements promulgated through a lawmaking process where "the Federal Government has weighed the competing interests relevant to the particular requirement in question, reached an unambiguous conclusion about how those competing considerations should be resolved in a particular case or set of cases, and implemented that conclusion via a specific mandate on manufacturers or producers." 518 U.S. at 501. Neither of these are present here in this 510(k)-cleared medical device litigation, and neither *Lohr* nor *Riegel* suggest any other source that might create federal requirements appropriate for express preemption.

Lohr and *Riegel* made sweeping statements about the differences between 510(k) clearance and PMA approval, and held that 510(k) review does not establish federal requirements like PMA approval does. Neither case suggested that special controls assigned to Class II devices substitute for or act as the "requirements" that might lead to express preemption under 360k(a). In fact, *Lohr* explicitly recognized the presence of "special controls" applicable to Class II devices yet still pointed out that—in contrast to devices subject to rigorous PMA-approval—510(k)-cleared devices still "may be marketed without advance approval." 518 U.S. at 477; *see also Riegel*, 552 U.S. at 317. Thus, even when Class II devices cleared through 510(k) pre-market notification are subject to special controls, the 510(k) process remains "one focused on equivalency rather than safety." *Riegel*, 552 U.S. at 317, 323.

b. There are no design controls for IVC filters.

The FDA has not promulgated design controls specific to IVC filters in any counterpart regulation. The absence of regulatory activity for filter design is conspicuous given 21 C.F.R.

§§ 1010-1050, in which FDA has promulgated design controls for multiple products. FDA has promulgated counterpart regulations that are both device- and disease-specific for many other 510(k)-cleared medical devices with regard to warning language, but not for IVC Filters. *See* 21 C.F.R. § 801, subpart H – "Special Requirements for Specific Devices."[11] In the absence of any counterpart regulation related to Plaintiffs' claims (e.g., failure to warn), courts consistently deny preemption challenges. *See James v. Diva Intern., Inc.*, 803 F. Supp. 2d 945, 951-52 (2011).

Bard cites to a few, rare exceptions to this rule where courts have found that certain claims arising from the use of Class II 510(k)-cleared medical devices are preempted based on device-specific counterpart regulations promulgated with specific warning language.[12] These cases are distinguishable from the claims in this litigation and the regulatory history of Bard's IVC filters for several reasons. First, the counterpart regulations in the cases Bard relies upon mostly involve over-the-counter, non-prescription devices sold to millions of lay people that all have very specific warning language under 21 C.F.R. § 801, subpart H. Here, there are no counterpart regulations or device- and disease-specific requirements. Indeed, the differences between two products for which preemption of warnings claims have been found—menstrual tampons and latex condoms—and Bard's IVC filters illustrate why Plaintiffs' claims are *not* preempted.

i. Menstrual Tampons – 21 C.F.R. § 801.430

The FDA has promulgated a specific counterpart regulation addressing user labeling for menstrual tampons regarding specific safety issues and diseases but that says nothing as to design requirements. 21 C.F.R. § 801.430.[13] This counterpart regulation contains *verbatim*

[11] Examples of products with counterpart regulations lower federal courts here found to specify certain labeling requirements: denture products for lay use (21 C.F.R. § 801.405); hearing aids (21 C.F.R. § 801.420); menstrual tampons (21 C.F.R. § 801.430); latex condoms (21 C.F.R. § 801.435).

[12] Notably, these decisions only preempted warnings claims, not design defect claims.

[13] *Papike*, 107 F.3d at 740-41 (stating that where the FDA promulgated a regulation mandating specific TSS warnings on tampon boxes and the regulation is device-specific (tampons) and disease-specific (TSS) it is distinguishable from prior MDA preemption cases including *Lohr* where federal labeling and manufacturing requirements reflected "important but entirely generic concerns about device regulation generally"); *see also Moore v. Kimberly-Clarke*, 867 F.2d 243, 246 (5th Cir. 1989); *Bejarano By & Through Bejarano v. Int'l Playtex*,

warning and labeling language for tampon products related to Toxic Shock Syndrome (TSS). This regulation requires tampon manufacturers to comply with the specific labeling language in the regulation. Thus any failure-to-warn claim based on an allegedly incomplete or misleading label would have to be preempted. But because the counterpart regulation does not address the design or construction of menstrual tampons, those claims are not preempted. *Moore v. Kimberly-Clarke*, 867 F.2d 243, 246 (5th Cir. 1989). In contrast, claims related to menstrual cups, having the same use and purpose as menstrual tampons and associated with the same disease (TSS), have not been subject to preemption even with regard to warnings claims because there exists no device-specific and disease-specific counterpart regulations for menstrual cups, and—like Bard's IVC filters—menstrual cups were 510(k)-cleared, not PMA approved. *See James*, 803 F. Supp. 2d at 949-52.

ii. Latex Condoms – 21 C.F.R. § 801.435

Similarly, the FDA has also promulgated a specific counterpart regulation for latex condoms containing verbatim labeling requirements found by some courts to preempt failure to warn claims.

> Similar to tampons, latex condoms are Class II medical devices regulated by the FDA… [a]s such, labels for condoms are regulated under the same rule subpart as tampons, 21 C.F.R. § 801, subpart H. Thus, latex condoms are regulated by the very same statute for device warnings that preempted the plaintiff's inadequate labeling and warning claims in *Moore* . . . . [b]ecause the FDA specifically regulates labels and warnings for latex condoms through 21 C.F.R. § 801.435, any claims for inadequate labeling and warning are preempted by federal law and should be dismissed with prejudice.

Rasheed v. Church & Dwight Co., 2012 WL 262619, at *8 (E.D. Tex. Jan. 12, 2012), *report and recommendation adopted*, 2012 WL 262616 (E.D. Tex. Jan. 30, 2012). Preemption of common law claims against manufacturers of Class II devices cleared via the 510(k) process

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Inc., 750 F. Supp. 443, 444-45 (D. Idaho 1990); *Krause v. Kimberly-Clark Corp.*, 749 F. Supp. 164 (W.D. Mich.1990); *Northrip v. International Playtex, Inc.*, 750 F. Supp. 402 (W.D. Mo. 1989); *Lindquist v. Tambrands*, Inc., 721 F. Supp. 1058 (D. Minn.1989); *Cornelison v. Tambrands, Inc.*, 710 F. Supp. 706 (D. Minn. 1989); *Meyer v. International Playtex, Inc.*, 724 F. Supp. 288 (D.N.J. 1988); *Lavetter v. International Playtex*, 706 F. Supp. 722 (D. Ariz. 1988); *Rinehart v. International Playtex, Inc.*, 688 F. Supp. 475 (S.D. Ind. 1988); *Edmondson v. International Playtex, Inc.*, 678 F. Supp. 1571 (N.D. Ga. 1987); *Stewart v. International Playtex, Inc.*, 672 F. Supp. 907 (D.S.C. 1987); *Poloney v. Tambrands, Inc.*, 412 S.E.2d 526 (Ga. 1991); *Lulov v. Tambrands, Inc.*, 198 A.D.2d 479, 604 N.Y.S.2d 206 (App. Div. 1993); *Berger v. Personal Prods., Inc.*, 797 P.2d 1148 (Wash. 1990).

predominantly occurs when there are counterpart regulations set as special controls that are not only device-specific, but also disease-specific as well. *See Merancio v. Smith & Nephew, Inc*., 2017 WL 2257124, at *6, n. 7 (E.D. Cal. May 23, 2017) (citing *Papike* which held that where FDA promulgated product and disease specific regulations with respect to a Class II device, preemption could be found).

Bard does not cite to any detailed counterpart federal regulation applying specifically to IVC filters because none exists. Therefore, unlike where specific counterpart regulations have been promulgated and codified in 21 C.F.R. § 801 (subpart H), Bard's preemption argument fails the first prong of the 21 C.F.R. § 808.1(d) test.

c. Even on the rare occasion where claims related to a 510(k) device have been preempted without a counterpart regulation, the facts are clearly distinguishable.

Bard cites two cases in which claims arising from a 510(k)-cleared product were preempted despite the absence of specific counterpart regulations under 21 C.F.R. § 808.1(d). These decisions only preempted failure to warn claims, and one is vacated. *Degelmann v. Advanced Med. Optics, Inc.*, 659 F.3d 835, 838-39 (9th Cir. 2011), *vacated*, 699 F.3d 1103 (9th Cir. 2012); *Tuttle v. CIBA Vision Corp.*, 2007 WL 677134 (D. Utah 2007) (granting preemption as to failure to warn claims; design defect claims dismissed on non-preemption grounds). Indeed, this Court has acknowledged that *Degelmann* is not good law, and even if it was would be limited to its specific facts. *Placencia*, 2012 WL 5877624, at n.3 (noting that *Degelmann* "turned on a specific and detailed directive the FDA issued for contact lens solutions passing through the 510(k) approval process").

Both *Tuttle* and *Degelmann* deal with a 1997 comprehensive guidance document assigned as a special control to contact lens solutions.[14] As a threshold matter, guidance documents like the one at issue in the contact lens cases or the 1999 FDA guidance on IVC filters[15] are not binding, they merely represent the FDA's current thinking on a matter and the FDA admonishes that guidance documents do not establish legally enforceable

[14] SSOF Ex. 2 at Ex. Y Guidance for Industry – Premarket Notification (510(k)) Guidance Document for Contact Lens Care Products).

[15] SSOF Ex. 2 at Ex. U (FDA Guidance for Cardiovascular Intravascular Filter 510(k) Submissions (Nov. 26, 1999) ("IVC Guidance document" or "1999 Guidance").

requirements—they are only recommendations. *See* 65 Fed. Reg. 56,468 (Sep. 19, 2000) (to be codified in 20 different parts of 21 C.F.R.); 62 Fed. Reg. 8961, 8963 (Feb. 27, 1997) (to be codified at 21 C.F.R. pt. 10). Upon issuance of a regulation, the FDA provides industry, academia, and other stakeholders with information on how the FDA intends to apply the regulation. This makes them non-binding and only demonstrative of what the FDA is *thinking*. 62 Fed. Reg. at 8963*; see also Christensen v. Harris County*, 529 U.S. 576, 587-588 (2000); *United States v. Mead Corporation*, 533 U.S. 218, 234 (2001); *Barnhart v. Walton*, 535 U.S. 212, 213 (2002). Even the 1997 guidance document upon which the *Degelmann* and *Tuttle* decisions were based stated:

> This document represents the agency's current thinking on the preparation of 510(k)s for contact lens care products. It does not create or confer any rights for or on any person, and does not operate to bind FDA or the public. An alternative approach may be used if such approach may be used if such approach satisfies the requirements of the applicable statue, regulations, or both.

SSOF Ex. 2 at Ex. Y at 1.

Thus, under *Lohr*, *Riegel*, and the Federal Register, even the onerous contact lens solution controls are not federal "requirements" within the preemption purview. *See* 42 Fed. Reg. 30351, 30384 (June 14, 1977) (codified at 21 C.F.R. § 808.1). A preempting FDA requirement will become applicable to a device within the meaning of section 360k only after FDA takes a *regulatory or administrative action involving the application of a particular requirement of the act to a particular device*.[16] *Id.*

Despite the lack of specific regulatory requirements, the *Degelmann* and *Tuttle* courts found plaintiffs' claims preempted due to the contact lens solution guidance document's extensive and inflexible labeling requirements specific to TSS.

> In order for a contact lens care solution to be labeled as a contact lens "disinfecting solution," [1] it should meet the primary performance criteria of the stand-alone procedure for contact lens disinfecting products . . . . Accordingly, with regard to the labeling at issue in this law suit, the FDA has promulgated specific requirements, which MoisturePlus met.

Degelmann, 659 F.3d at 841-842.

[16] There is no evidence in the IVC Filter Guidance document setting forth regulatory or administrative requirements specific to IVC filters. SSOF ¶¶ 23-34.

The guidance document that served as a special control for contact lens solutions in *Degelmann* and *Tuttle* contained extensive and very specific information regarding the products to which it applied, 172 pages worth. And the comprehensive information found in the contact lens guidance document includes precise directions for the design of clinical testing including the number of subjects, specific biochemistry and other design details, standards for standalone performance, and—most importantly—is *both device- and disease*-specific. In both *Degelmann* and *Tuttle*, after determining that this guidance document assigned as a special control for contact lens products qualified as a "federal requirement" that could invoke preemption (which plaintiffs here dispute under the authorities above), the courts pointed out the specific labeling language in the guidance document as the basis for preempting the plaintiffs' failure-to-warn claims.

In stark contrast to the 1997 contact lens solution guidance document, the 1999 IVC Guidance applicable to all IVC filters is a mere 12 pages and does not contain any specific labeling language relevant to any filter complications or injuries at issue in this MDL. SSOF 34; SSOF Ex. 2 at Ex. U. There are no design requirements, safety or risk criteria filters must meet, or standards for threshold performance. In other words, there is nothing specific to Bard's retrievable filters (device-specific) in any of the documents assigned as special controls to IVC filters. Nor could there be since the 1999 guidance document was issued by FDA before Bard's retrievable filters underwent 510(k) review. SSOF 19-42.[17]

Thus whatever the basis of preemption against contact lens solution manufacturers, the special controls for IVC filters cannot invoke preemption under 21 C.F.R. § 808.1(d). Guidance documents assigned as special controls that do not mandate performance standards or other design controls cannot be deemed federal requirements. *Thompson*, 2015 WL 7888387, at *9-11 (denying preemption because special control guidance document for orthopedic bone cement did not dictate performance standards or other specific requirements). For example, in *Thompson* the court was faced with a very similar guidance document in

[17] The other special controls for IVC filters (ISO 10993 and 510(k) sterility guidance) are generic requirements for all implantable medical devices and offer nothing specific to IVC filter labeling or design. SSOF 20-22.

length and lack of specific substantive mandates as the 1999 Guidance for IVC filters, but one wholly unlike the contact lens guidance. The *Thompson* court determined that the contact lens guidance contained stand-alone performance standards, yet the court did not agree that the bone cement guidance document, in the absence of device-specific standards of any kind, amounted to a federal requirement. *Id.* at *9; *accord Placencia,* 2012 WL 5877624, at n.3 (distinguishing *Degelmann* because contact lens guidance document involved "a specific and detailed directive . . . for contact lens solutions"). The court held that the recommendations in the guidance did not rise to the level of a federal requirement:

> The guidance document, while certainly providing important recommendations for the submissions under the 510(k) process, does not *mandate* any particular performance standards relating to, for example, the particle size, variation in particle size, viscosity.

Id. at 10.

As in *Thompson*, the 1999 IVC Guidance does not contain specific information or device-specific and disease-specific mandates in order to meet the definition of a federal requirement under 21 C.F.R. § 808.1(d). SSOF 34, 19-42. And like the guidance document in *Thompson*, it is merely a guide to assist with the 510(k) submission, not a recipe for designing IVC filters or their labels. Even Bard's own witness admits that the 1999 guidance for IVC filters is not a requirement and its own experts rely on information indicating that special controls are merely part of the substantial equivalence evaluation. SSOF 13, 24. There is no precedent[18] or authority for Bard's argument that the brief and non-mandatory suggestions from the FDA are a "federal requirement" conferring express preemption.

2. Bard also fails the second part of 21 C.F.R. § 808.1(d) because there are no other federal requirement specific to its filters and Bard's FDA communications do not create a federal requirement.

Unable to establish that there are device-specific federal requirements for its IVC filters, Bard claims that the 510(k) process through which its filters were cleared to market

[18] Tellingly, the only authority Bard cites for the proposition that there are divergent views regarding express preemption are PMA cases. *See Caplinger v. Medtronic*, 784 F.3d 1335, 1337 (10th Cir. 2015); *Mutual Pharmaceutical Co., Inc. v. Bartlett*, 133 S. Ct. 2466 (2013).

imposed specific requirements on its devices. This is wrong, both legally and factually.[19] The 510(k) review process does not set federal requirements, even if it were extremely rigorous, because 510(k) review is not a safety review, but rather an exception to it. *Riegel*, 552 U.S. at 322-23. Indeed, Bard's voluminous Statement of Facts demonstrates that most of the contact between the FDA and Bard over the 17 years it has been in the retrievable-filter business is in accordance with the FDA's purview to request more information pursuant to 21 C.F.R. § 807.87(*l*) as part of its substantial equivalence review of Bard's 510(k) submission. Motion at 8, 24.

Not only is there no legal precedent for a 510(k) review to set a federal requirement for a successful express preemption challenge (no matter how many 510(k) submissions based on the same line of predicate devices), Bard has provided no facts indicating that FDA's 510(k) review of Bard's filters rose to the level of a PMA review establishing an independent showing of safety and effectiveness, i.e., a federal requirement. SSOF 4-7, 9-10, 15-18, 42. Thus, Bard's attempt to fashion a "requirement" out of a lengthy recitation of its exchanges with the FDA during the multiple 510(k) reviews of its six filters is unavailing.

The chart attached at Ex. R to SSOF Ex. 2 digests and distills Bard's communications with the FDA, which are irrelevant to preemption. First, of the fifteen[20] 510(k) submissions Bard filed with its Statement of Facts, only ten are directly attributable to actual filters. SSOF 7-8. Five submissions relate to changes to the delivery systems (not the implantable filter) or changes to brochures or marketing materials. SSOF 7-8. There are also 15 exhibits attached to

[19] Bard's 818 Statements of Fact are misleading and in some instances factually incorrect. As only one example among many, Bard argues on page 28 that it is prohibited from making unilateral label changes. But new warnings neither require FDA approval nor a 510(k) submission. Rather, manufacturers should promptly update warnings and contraindications should be implemented immediately. *See* Bard's Ex. G, Deciding When to Submit a 510(k) for a Change to an Existing Device, at 11 (stating that "manufacturers are encouraged to add new contraindications to their labeling and to notify existing users of their device as expeditiously as possible whenever a pressing public health need arises"). But there is no need to exhaustively detail all of Bard's inaccurate characterizations of the 510(k) process because fundamentally a 510(k) is equivalence not safety review and thus cannot preempt Plaintiffs' claims.

[20] Bard has submitted sixteen 510(k) submission in its exhibits to declarations, but one is submitted twice in the form of a special and then a traditional 510(k). Carr Dec. Exhs. 43, 54.

the Carr and VanVleet declarations that represent letters indicating that substantial equivalence has been determined.[21] Between 510(k) submissions and FDA letters determining substantial equivalence after 510(k) review, this equates to 42 exhibits submitted to the court that are not relevant to its preemption argument in the sense that there is no doubt these comprise nothing more than the 510(k) process.

Second, 20 exhibits are logistical or administrative interactions with FDA including correction of typographical errors or requesting and receiving extensions to respond to deficiencies. SSOF Ex. 2 at Ex. R. Besides Bard's internal contact memos, notes, and emails, there are only 122 substantive exchanges with FDA over a seventeen (17) year period beyond the 510(k) submissions themselves, and several of these are requests for information from Bard because its 510(k) submissions contained deficiencies. *See id.* Much of the basis for Bard's claims that the FDA took so much time with some of its applications can be traced back to FDA's multiple deficiency letters to Bard,[22] and a few dozen FDA requests for information hardly elevate IVC filter 510(k)-clearance review to the level of the PMA process. *Cf. Lohr*, 518 U.S. at 477 (describing based on citations to Congressional hearings that for PMA approval medical device manufacturers "must submit detailed information regarding the safety and efficacy of their devices, which the FDA then reviews, spending an average of 1,200 hours on each submission"). All of Bard's communications with the FDA regarding its IVC filters were within a typical 510(k) review process where FDA can and does request additional information as demonstrated by the flowchart of substantial equivalence determination upon which Bard's FDA regulatory expert relies. SSOF 13. The *ad nauseam* rendition of FDA communications Bard recites demonstrate precisely why medical-device plaintiffs have consistently and successfully moved *in limine* to exclude this sort of evidence in order to avoid mini-trials on voluminous FDA-related communications that have nothing to

[21] Carr Dec. Exs. 7, 12, 21, 23, 58, 67, 98, 100, 103, 114, 119, 124, 126, 128. VanVleet Dec. Ex. 36, 79.

[22] Examples of FDA's frequent requests to cure deficiencies in Bard's submission can be found at Carr Exs. 10, 46, 59, 84, 93, 94, 96,105, 109, 116-117, 122, and VanVleet Exs. 6, 12, 33, 73.

do with the safety of the product. SSOF 67; *see also Huskey v. Ethicon, Inc.*, 848 F.3d at 160-163; *Cisson)*, 810 F.3d at 920-23.

Bard further argues that its Investigational Device Exemption (IDE) submissions to FDA related to its EVEREST and Denali clinical studies somehow confer preemption. Yet it provides no rationale for why this would be so in the 510(k) substantial equivalence review context. None of the case law Bard cites involved an IDE conducted prior to determination of substantial equivalence, only PMA review. Bard does not even attempt to argue that the IDE submissions and review create a federal requirement under 21 C.F.R. § 808.1(d), nor does the case law it cites include a product that was already cleared by a 510(k) review and on the market when the IDE activities were ongoing. *Cf. Oja v. Howmedica*, 111 F.3d 782, 788-89 (10th Cir. 1997) (rejecting hip implant manufacturer's arguments that discussions with FDA in 1983 and 1991 to obtain 510(k) approval for device including IDE study of cementless use constituted specific regulation, citing and quoting *Lohr*).

For instance, the product at issue in the EVEREST retrievability study, the G2, was already on the market via the 510(k) process prior to Bard's IDE for the EVEREST study; it had received a substantial equivalence determination, not PMA approval. Carr Dec., Ex. 69 at BPV-17-01-00122845. Similarly, the IDE for the Denali clinical study was submitted to FDA on December 30, 2010, and was not completed before the 510(k) submission was sent to FDA for the Denali filter on February 8, 2013. VanVleet Exs. 45 and 66a. In fact, the day prior to when the Denali 510(k) was submitted the FDA was still asking questions and pointing out deficiencies in the Denali IDE annual report. VanVleet Ex. 65. The Denali IDE clinical study (which examined placement and retrievability, not long-term safety) final report was not closed until February 2016, three years after Denali was already being sold and not until approximately four months *after* the first Denali case—a filter fracture—was filed in this MDL.[23] Given that the Denali filter had received a substantial equivalence determination letter prior to the Denali study even being complete, it could not have been outcome determinative with regard to new issues of safety[24] that might arise in the 510(k) process when

[23] *Rouse v. C.R. Bard, Inc., et al*, 2:25-cv-02227-DGC (October 4, 2015).
[24] There can be no new issues as to efficacy as the study was not well-controlled. SSOF 52.

comparing to its predicate device, the Eclipse. Moreover, neither the EVEREST nor the Denali studies examined the safety and effectiveness of the filters in well-controlled studies required to demonstrate effectiveness of the filters; they were solely retrievability studies. SSOF 51-53.

Ultimately, in all but one review of Bard's 510(k) applications, FDA merely invoked its statutory power to require additional "safety and effectiveness" information from Bard as a condition for clearance based on substantial equivalence to a predicate, a back-and-forth between the FDA and the manufacturer that is inherent in the 510(k) review process. SSOF 12. In none of the filter-clearance submissions did the back-and-forth between Bard and the FDA raise the level of review beyond the 510(k) substantial equivalence standard because as part of that review "[t]he FDA may also request additional information in an effort to determine whether the device is substantially equivalent to a predicate device" for any medical device undergoing 510(k) review. *James*, 803 F. Supp. 2d at 947-48; *see also* 21 CFR § 807.87(l) (granting FDA authority to request additional information as part of 510(k) process). Similarly, because Bard's filters were cleared via the 510(k) process and Bard has not established that the clarifications, corrections, and additional information requested by FDA as part of the 510(k) clearance process equate to PMA approval, Bard's repeated reliance on *Horn v. Thoratec Corp.*, 376 F.3d 163 (3d Cir. 2004), is misplaced. Moreover, even *Horn* acknowledges that, where there is no federal requirement specific to a particular device, state law tort claims are not preempted. *Id.* at 168 & n.9 (discussing how lower courts have only found preemption for 510(k) cleared devices for "*some*, but not all" state tort claims where a federal requirement at issue is specifically applicable to a particular device.").

3. Despite Bard's voluminous submissions to the Court, key information about Bard's devices was withheld from FDA.

Bard's voluminous presentation of its version of its IVC filter story is misleading because it has not provided the Court or the public with material information it knew about the safety of its devices. As early as June 12, 1998, internal notes of a meeting between Dr. John Kaufman, who conducted an early animal study of Bard's proposed retrievable IVC filters, and Bard engineer and Declarant Robert Carr show that very early Bard executives and

researchers observed penetrations with the Recovery filter that were a "perhaps product killing problem." SSOF 57. These results were never submitted to the FDA, as part of the 510(k) submission for the Recovery filter or at any other time. SSOF 58. Bard's lead engineer. Mr. Carr, was presented with this information after the lead investigator was "troubled by the degree to which the arms protruded beyond the IVC wall" and "bothered by the apparent penetration of the filter elements." SSOF 59.

Also, FDA FOIA productions indicate that in November 2004 FDA was interested in seeing comparative failure rates between Bard's filters and its competitors. SSOF 54. Demonstrative of the optional rather than mandatory nature of 510(k) substantial equivalence review (as opposed to the exhaustive safety review in the PMA approval process), Bard never provided this data comparing failure rates between its filters and its competitors' even though Bard possessed these findings. SSOF 55. At his deposition on his Motion Declaration, Mr. Carr could only point to non-competitive test data comparing Bard's own filters (Recovery and Simon Nitinol), not Bard's filters with its competitors. SSOF 56. When Bard learned that the competitive testing data had not actually been shared with the FDA as represented to Bard's Board of Directors, it reported the error to Bard's President and Chief Operating Officer, but not the FDA. SSOF 55-56. Bard still has not shared this with the FDA.

To the extent Bard claims FDA guidance existed for post market surveillance of IVC filters, the FDA has clearly stated that Bard violated it. SSOF 71. More specifically, on July 13, 2015, the FDA sent a "Warning Letter" to Bard for, in addition to other violations, improperly evaluating and reporting adverse event complaints related to its IVC filters. *Id.*

Even in the face of its argument that state-law claims should be preempted because of an IDE it submitted for the EVEREST study, evidence exists that Bard did not share key information it had as to the results of that study with FDA. Specifically, the physician acting as medical monitor for the trial expressed concern in an October 26, 2006, meeting over the number of device events he noted in the study (but indicated it was not in his power to stop the study). SSOF 62-64. The medical monitor, Dr. Kandarpa, reviewed a draft table for a clinical report related to the EVEREST study with particular attention paid to the device observations

which outlined migration, tilt, and penetration as well as filter movements. SSOF 64. His concern rose to the level of questioning whether FDA should clear the G2 filter and suggesting that it be redesigned in view of the 66 percent adverse events experienced in the trial. SSOF 65. This information was not shared with the FDA.

4. Even if there were specific federal requirements applicable to Bard's IVC filters (there are not), Bard's Motion fails since there is no "careful comparison" with Plaintiffs' claims because there are no federal requirements to which to compare them.

Because there are no counterpart regulations specific to IVC filters and because neither the back-and-forth with the FDA, nor special controls for all IVC filters constitute federal requirements, one never even gets to the second step of the *Lohr*/*Riegel* preemption analysis. There is simply nothing to which one can "carefully compare" Plaintiffs' state law claims.

The claim-by-claim preemption analysis Bard attempts in its Motion is conclusory and misplaced. For Plaintiffs' design claims, Bard simply states that Plaintiffs' claims are different from that cleared by the FDA. There is no discussion of any specific requirement that the FDA imposed on Bard for the design of its IVC filters. This is, of course, because there are no specific design standards or requirements promulgated by the FDA and imposed during its 510(k) review; that review focused solely on substantial equivalence and not safety. Nor does Bard provide any proof of such design standards or requirements.

On Plaintiffs' warnings claims, Bard at least provides some record citations to attempt to show that there were purportedly specific warnings crafted by the FDA for Bard's IVC filters. But these arguments fail to hold up to scrutiny. The FDA communications referenced by Bard did not impose mandatory requirements for its IVC filter labeling and warnings rather only suggestions and requests which amount to negotiations. SSOF Ex. 2 at Ex. D at 92:1-4. Moreover, Bard admits that these requests for labeling from the FDA had nothing to do with safety. The FDA asked Bard to include in its labeling for the Recovery a statement that "[t]he safety and effectiveness of the Recovery Filter for use as a retrievable or temporary filter have not been established" during a time when its filters had no FDA clearance for retrievability. Bard SOF ¶ 80. And the Court is familiar with the *Arvizu* case, Bard's lone legal citation, which involved a PMA-approved medical device and thus provides no guidance on

preemption analysis 510(k)-cleared devices. Once again Bard cannot cite to either legal authority or the facts of FDA clearance of its devices to support preemption.

Finally, Bard's preemption analysis of Plaintiffs' breach-of-warranty claims is simply incorrect. As Bard conceds, Plaintiffs prevail on their claims if Bard IVC filters were not safe and effective. Motion at 26. But there is nothing about those findings that contradict anything the FDA ever did with IVC filters because the 510(k) clearance of the products had nothing to do with safety (or efficacy for that matter). Try as it might, Bard cannot twist 510(k) substantial equivalence review into a safety review imposing safety and efficacy design and labeling requirements that could invoke preemption.

E. Common law claims involving Bard's IVC filters are not subject to implied preemption.

1. Bard's implied preemption argument is contrary to Congress's intent, Supreme Court case law, and common sense.

Bard asks this Court to find implied impossibility preemption if it concludes that this case does not fall within the MDA's express preemption provision. No court has accepted Bard's argument in the medical device context, and the judge responsible for a major MDL involving medical devices flatly rejected it. The Hon. Joseph Goodwin presides over several MDLs for pelvic mesh products, which at the time of his order encompassed approximately 70,000 cases. *Mullins v. Ethicon, Inc.*, 147 F. Supp. 3d 478, 479 (S.D. W. Va. 2015). Judge Goodwin rejected the exact same implied preemption argument Bard makes here. "[Defendants'] spin on impossibility preemption would destroy state tort liability for any product subject to even the least rigorous federal regulatory scheme. . . . Congress, the Supreme Court, and common sense counsel against such a result." *Id.* at 481.

As a starting point, there is a long-standing presumption against implied preemption. *See Arizona v. United States*, 567 U.S. 387, 400 (2012) (stating that "courts should assume that the historic police powers of the States are not superseded unless that was the clear and manifest purpose of Congress" (quotations omitted)). The presumption against implied preemption is particularly strong where, as here, Congress has spoken to the breadth of preemption through an express preemption clause. *See Cipollone v. Liggett Group, Inc.*, 505

U.S. 504, 517 (1992) ("Congress' enactment of a provision defining the pre-emptive reach of a statute implies that matters beyond that reach are not pre-empted."). Bard claims that there is no longer such a presumption but the case Bard cites to, *Puerto Rico v. Franklin Calif. Tax-Free Trust*, involved an *express* preemption clause and thus does not alter this strong bias against *implied* preemption. 136 S. Ct. 1938, 1946 (2016). Of course, as stated in *Lohr*, there can be ambiguities that surround even express preemption clauses. *Lohr*, 518, U.S. at 489.

Congress cannot have intended to implicitly preempt every design-based claim against every medical device manufacturer when it has explicitly said otherwise. As the *Mullins* court noted, acceptance of Bard's argument would inoculate all medical device manufacturers against tort liability for defective design or negligent design, even though their products are not subject to pre-market review for safety and efficacy. *Mullins*, 147 F. Supp. 3d at 479. It is wholly illogical to conclude that Congress had this intent; otherwise, the express preemption clause would have been written differently.

The Supreme Court has also rejected Bard's implied preemption argument. In *Lohr*, the Court considered whether the MDA preempted state-law claims for negligence and strict liability/design defect. 518 U.S. at 474, 484. The Court concluded that Congress intended to preserve the "status quo" of medical device manufacturer liability for state tort law claims:

> There is no suggestion in either the statutory scheme or the legislative history that the § 510(k) exemption process was intended to do anything other than maintain the status quo with respect to the marketing of existing medical devices and their substantial equivalents. **That status quo included the possibility that the manufacturer of the device would have to defend itself against state-law claims of negligent design.** Given this background behind the "substantial equivalence" exemption, the fact that "[t]he purpose of Congress is the ultimate touchstone" in every pre-emption case, and the presumption against pre-emption, the Court of Appeals properly concluded that the "substantial equivalence" provision did not pre-empt the Lohrs' design claims.

Lohr, 518 U.S. at 494 (emphasis added, internal citation omitted). And, as the *Mullins* court noted, although determining the purpose of Congress can be difficult, "[h]ere, [the] task is made easy because the Supreme Court has already examined the purpose of the federal law at issue and determined that Congress did not intend to preempt state law design defect claims cleared through the 510(k) process." 147 F. Supp. 3d at 482 (citing *Lohr*, 518 U.S. at 494).

2. Bard's "conflict" preemption argument fails because the 510(k) process addresses substantial equivalence, not safety, and thus cannot "conflict" with state tort law imposing safety requirements on medical devices.

Bard's implied preemption argument is based on the concept of "conflict" preemption, that supposedly it cannot comply with a state-law demand of a safer product because Bard cannot change its product without federal approval. But "[i]mpossibility preemption is a demanding defense," *Wyeth v. Levine*, 555 U.S. 555, 573 (2009), and Bard cannot establish it here because the FDA 510(k) process governing alterations of a product does not conflict with Bard's duties under state law not to design, manufacture, or sell defective products. As the *Mullins* court held, "The state safety requirement does nothing to undermine or interfere with the federal law because the federal law does not make specific demands on safety. State law does not pose an obstacle to, frustrate the purpose of, undermine, interfere with, impede, or otherwise make it impossible to comply with federal law." *Mullins*, 147 F. Supp. 3d at 481. In other words, because the 510(k) process evaluates equivalency, not safety, there is no federal barrier to improving the safety of an existing product. *See id.* at 481-82 ("The defendants' definition of impossibility would find preemption notwithstanding the absence of any state interference with federal law, a rule without basis in the Supremacy Clause.").

3. *Mensing* and *Bartlett* involve generic drugs, which operate under a different regulatory scheme lacking an express preemption clause.

Bard's final argument is to analogize this case to the Supreme Court decisions involving preemption for generic drugs. *See Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466, 2472 (2013); *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 608 (2011). Bard cites no case on point in support of this argument, and at least two cases have rejected it. *See Mullins*, 147 F. Supp. 3d at 481; *In re Depuy Orthopedics Pinnacle Hip Implant Prods.*, No. 3:11-cv-03590-K, 2014 WL 3557392, at *10-11 (N.D. Tex. July 8, 2014) (holding that the manufacturer "could not have been subject to conflicting state and federal design requirements" because the FDA's 510(k) process "imposed no requirements for safety or otherwise on it").

In *Mensing* and *Bartlett*, the Court held that it was impossible, under federal law, for the manufacturer to give different warnings or to alter the drug's chemical composition from those of by the brand-name manufacturer to keep the generic drug exactly the same as its

brand-name counterpart. *Bartlett*, 133 S. Ct. at 2471, 2480; *Mensing*, 564 U.S. at 613, 618. But there is no such duty of sameness here. "The impossibility in *Mensing* arose from the unique 'duty of sameness' imposed on generic drugs, which has no corollary in the medical device context." *Mullins*, 147 F. Supp. 3d at 484.

Bard appears to claim that it could not have made any alterations to its devices or labeling because of the FDA's 510(k) clearance process. This argument too has been rejected. "Unlike the law imposing the duty of sameness for generics, there is no federal law prohibiting design changes to medical devices, particularly changes representing advances in safety." *Mullins*, 147 F. Supp. 3d at 485. "The law simply requires that manufacturers making a 'significant change' submit another 510(k) notification, which the FDA will clear if it determines the device is substantially equivalent to a device already on the market." *Id.* Bard could have made a safer product in the first instance, or changed the product to any alternative that would pass the FDA's 510(k) equivalency review. Notably, one of the safer alternatives proposed in this litigation (and by Bard itself) is Bard's own Simon Nitonol Filter ("SNF"),—so obviously there are "possible" alternatives. SSOF 70.

Bard argues that *Mullins* predated certain circuit decisions that purportedly apply *Bartlett* to brand-name drugs. The authorities are mixed on whether *Bartlett* preemption applies to cases involving brand-name drugs.[25] *Compare Yates v. Ortho-McNeil-Janssen Pharm., Inc.*, 808 F.3d 281, 300 (6th Cir. 2015), *with Young v. Bristol-Myers Squibb Co.*, 2017 WL 706320, at *8 (N.D. Miss. Feb. 22, 2017); *Brazil v. Janssen Research & Dev. LLC*, 2016 WL 4844442, at *16–17 (N.D. Ga. Mar. 24, 2016); *Sullivan v. Aventis, Inc.*, 2015 WL 4879112, at *5-6 (S.D.N.Y. Aug. 13, 2015). But even if *Bartlett* preemption does apply to brand-name *drugs*, that fact has no bearing on *medical devices*. While a brand-name drug must go through a rigorous pre-market approval process to ensure the drug is safe, *Bartlett*, 133 S. Ct. at 2470-71, a medical device typically only undergoes 510(k) equivalency review. And there is no express preemption in the FDA's regulatory scheme for prescription drugs.

[25] The First Circuit case cited by Bard is inapposite because the court held that there was no new post-approval information or analysis that could have triggered the CBE process by which brand-name manufacturers may unilaterally alter their labels. *See In re Celexa & Lexapro Mktg. & Sales Practices Litig.*, 779 F.3d 34, 38 (1st Cir. 2015).

Because the MDA has an express preemption provision, there is a strong presumption against implied preemption in the medical device context. *Cipollone*, 505 U.S. at 517.

Bard cites only one case from outside of the drug context, and that case is wholly inapposite. *See Sikkelee v. Precision Airmotive Corp.*, 822 F.3d 680, 709 (3d Cir. 2016) (addressing field preemption in the context of airline regulations and holding that claims were *not* preempted). As a court evaluating a case involving insecticides recognized, *Mensing* and *Bartlett* are only useful precedents for other drug cases. *See Ansagay v. Dow Agrosciences LLC*, 153 F. Supp. 3d 1270, 1285 (D. Haw. 2015) (holding that even if *Mensing* and *Bartlett* could be applied to brand-name drugs, they would be inapplicable to the preemption analysis under FIFRA). For preemption purposes, medical devices are much more analogous to insecticides than to drugs because like the MDA, FIFRA has an express preemption provision—and thus there is a presumption against implied preemption. *See id.* at 1282 (citing *Bates v. Dow Agrosciences LLC*, 544 U.S. 431 (2005), and stating that "once the Court concluded that the claims were not expressly preempted, it would have been inconsistent for the Court to have concluded that FIFRA somehow impliedly preempted those same claims").

Because Congress has spoken through its express preemption in the MDA, there is no need to also explore implied preemption. This Court should reject Bard's argument based on implied conflict preemption—as every court presented with the same argument has done.

IV. CONCLUSION

Plaintiffs' claims are not subject to express or implied preemption and Bard's Motion should be denied.

RESPECTFULLY SUBMITTED this 1st day of September, 2017.

GALLAGHER & KENNEDY, P.A.

By:*/s/ Mark S. O'Connor*
Mark S. O'Connor
2575 East Camelback Road
Phoenix, Arizona 85016-9225

LOPEZ McHUGH LLP
Ramon Rossi Lopez (CA Bar No. 86361)
(admitted *pro hac vice*)

100 Bayview Circle, Suite 5600
Newport Beach, California 92660

HEAVISIDE REED ZAIC
Julia Reed Zaic, Esq. (CA Bar No. 224671)
(admitted *pro hac vice*)
Laura Smith, Esq. (CA Bar No. 313879)
(admitted *pro hac vice*)
312 Broadway, Suite 203
Laguna Beach, California 92660

Counsel for Plaintiffs

CERTIFICATE OF SERVICE

I hereby certify that on this 1st day of September, 2017, I electronically transmitted the attached document to the Clerk's Office using the CM/ECF System for filing and transmittal of a Notice of Electronic Filing.

/s/ Gay Mennuti

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